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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,958	12/19/2003	Sophia Kossida	004974.00951	3681

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,958	KOSSIDA ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 16-17, 20, 51, 53, 55-56, and 61-63, 65, drawn to DNA encoding human sphingosine kinase-like proteins (referred to as "kinases" from now on), methods of expressing said sequences, kits comprising said sequences, , pharmaceutical compositions comprising said sequences, and oligonucleotides that hybridize to said sequences, classified in class 435, subclass 194.

II. Claims 10-15 and 23, drawn to said kinases, kits and fusion proteins comprising said kinases, classified in class 435, subclass 194.

III. Claims 18-19, drawn to methods of use of said DNA sequences in a hybridization assay, classified in class 435, subclass 6.

IV. Claims 21-22, 49-51, 54 and 64, drawn to antibodies which bind said kinases, pharmaceutical compositions comprising said antibodies and methods of use of said antibodies, classified in class 435, subclass 7.1.

V. Claims 24-48 and 75, 77, drawn to methods of screening for modulators of said kinases or apoptosis inducing agents, classified in class 435, subclass 15.

VI. Claims 51-52 drawn to a pharmaceutical composition comprising ribozymes, classified in class 514, subclass 12.

VII. Claims 57-60, drawn to methods of treatment using modulators of said kinases, classified in class 514, subclass 789.

VIII. Claims 66-74, drawn to method of inducing apotosis utilizing an apoptosis inducing agent, classified in class 514, subclass 12.

IX. Claims 76, drawn to apoptosis inducing agents, calssification unknown. This is because classificationdepns on the chemical structure of the agent and applicant has not defined the chemical structure of said agent.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I, the polypeptides of Group II, the antibodies of Group IV, the ribozymes of Group VI and the apoptosis inducing agents of Group IX are each patentably distinct from the other because each product is directed to an unrelated chemical structure and function.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Groups I may be used for recombinant expression of said kinases which is a totally different method than methods of Groups III.

The DNA of Group I is unrelated to any of the methods of Groups V, VII and VIII because said products are neither made nor used by any of said methods.

The polypeptides of Group II are unrelated to any of the methods of Group III, VII and VIII because said products are neither made nor used bu said methods.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptids of Group II may be used for antibody preparation which is totally different method that of Group V.

The antibodies of Group IV are unrelated to any of the methods of Group III, V, VII and VIII because said products are neither made nor used by any of said methods.

The ribozymes of Group VI are unrelated to any methods of Group III, V, VII and VIII because said products are neither made nor used by any of said methods.

The apoptosis inducing agents of Group IX are unrelkated to any of the mthods of Groups III, V and VII because said products are ntiher made nor used by any of said methoids.

Inventions IX and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case UV radiation may

be usred foir induction of apoptosis which is a totally different product than thjat of Group IX.

The methods of Groups III, V, VII and VIII are each patentably distinct from the other because each method has different steps and different end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their separate classification, restriction for examination purposes as indicated is proper.

Claims 1-10, and 14-77 are generic to a **plurality of disclosed patentably distinct species** comprising SEQ ID NO:2, 10 and 11, structurally distinct enzymes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or other wise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and he rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an alerted product claims is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined, See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maryam Monshipouri Ph.D.

Primary Examiner

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